IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

THE UNITED STATES OF AMERICA, *ex rel.* DONALD GALE,	)	Case No. 1:10-CV-0127
Plaintiff,	)	Judge James S. Gwin
vs.	)	
OMNICARE, INC.,	)	
Defendant.	)	

MEMORANDUM IN SUPPORT OF RELATOR'S MOTION TO EXCLUDE THE EXPERT REPORT OF DR. MOHAN RAO, PH.D

Defendant's proffered expert, Dr. Mohan Rao, Ph.D, has presented a report that is based upon no more than fanciful speculation and rote recitation of Omnicare's unfounded characterizations of the facts of this case. Dr. Rao incorrectly uses a "market analysis" to opine that Omnicare's *per diem* arrangements were "economically rational." As shown below, because they are inapplicable to the federal healthcare system and regulatory scheme, Dr. Rao's methods are unreliable. Further, he misapplies his method to the facts of the case in his analysis of "loss leaders" and the risk share analysis. Further still, several of his conclusions—including that Omnicare's use of *per diem* contracts is low, the purportedly competitive market in which it operates, and that there exists no evidence of harm to the government—are irrelevant and not based on sufficient facts or data.

Dr. Rao's conclusions are neither premised upon accepted methods of economic analysis, nor legally relevant. As such, his report is wholly unreliable under the standards of *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993), and this Court should exclude it in its entirety.

I. LEGAL STANDARD

In *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993), the Supreme Court articulated the standard by which trial courts evaluate expert testimony pursuant to Federal Rules of Evidence 702 and 104(a). Under this standard, now codified in Rule 702, expert testimony (1) must "help the trier of fact to understand the evidence or to determine a fact in issue"; (2) must be made by a "qualified" individual; (3) must be "based on sufficient facts or data"; (4) must be the "product of reliable principles and methods"; and (5) must be the result of a reliable application of those principles or methods to the facts of the case. *See* Fed. R. Evid. 702. Taking these requirements together, "[t]he predominant lesson of *Daubert* is that federal courts are not simply to take the expert's 'word for it.'" *Haller v. Astrazeneca Pharms. LP*, 598 F. Supp. 2d 1271, 1299 (S.D. Fla. 2009).

With respect to expert testimony of a non-scientific nature, the trial court is expected to "make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999). The party proffering testimony has the burden of proving its admissibility by a preponderance of the evidence. *Nelson v. Tennessee Gas Pipeline Co.*, 243 F.3d 244, 251 (6th Cir. 2001).

In addition to meeting the standards of *Daubert* and Rule 702, expert evidence, of course, must satisfy *all* requirements of admissibility. Among those requirements is that expert evidence must be relevant under Rules 401 and 402. *See, e.g.*, *United States v. Ashraf*, 628 F.3d 813, 827 (6th Cir. 2011) (noting that, under *Daubert*, the "subject matter of an expert's testimony must be relevant to the case"). And its probative value must outweigh its potential for unfair prejudice or confusion under Rule 403. *See, e.g.*, *United States v. Thomas*, 167 F.3d 299 (6th Cir. 1999) (affirming district court's exclusion of polygraph evidence which, even if not excludable under *Daubert*, failed Rule 403's balancing test).

II. DR. RAO'S REPORT FAILS TO SATISFY *DAUBERT* OR THE FEDERAL RULES OF EVIDENCE.

A legal argument annotated with quotations from articles and textbooks does not an expert report make. To be admissible under Rule 702, an expert's opinion must have "a reliable basis in the knowledge and experience of the [expert's] discipline." *Jahn v. Equine Servs., PSC*, 233 F.3d 382, 388 (6th Cir. 2000) (quoting *Daubert*, 509 U.S. at 592). But some of Dr. Rao's conclusions are based on little more than speculation; others merely parrot Defendant's legal or factual contentions; and others are legally irrelevant because they ignore critical and even undisputed facts from the record in this case. These conclusions should be excluded.

A. Dr. Rao's application of market-based valuation is unreliable and inapplicable to this case because it ignores facts about the industry and governing regulatory scheme.

Dr. Rao spends much of his time in the report arguing that the market for institutional pharmacy services is competitive. *See* Rao Report ¶¶ 43-68. Dr. Rao's conclusion that the market is competitive forms the basis for his claim that "[t]he Medicare Part A per diem rates offered by Omnicare are not consistent with 'kickbacks'; rather they reflect rational pricing to win SNF business from other competing institutional pharmacies." *Id.* ¶ 68. This conclusion flies in the face of obvious reality: competition and illegal pricing are not mutually exclusive.

First, federal regulations make it *illegal* for a pharmacy to swap low *per diems* for other federal healthcare business, irrespective of competition. Even if it is economically "rational" to price Part A *per diem* rates at below Omnicare's own cost (because of the other business Omnicare gains as a result), such pricing is *also* an illegal inducement. Thus, the fact that (1) a given pharmacy prices near the competition cannot yield the conclusion that (2) the price is not an illegal kickback. Second, Dr. Rao ignores the fact that other players in the market might *also* be engaged in illegal swapping. Dr. Rao's two errors can be summarized simply: it is not true that Omnicare must *either* be engaged in illegal kickbacks *or* operating in a competitive environment, because Omnicare may be doing *both*. As this Court has ruled, fair market value "is not simply what others in the industry would have charged for the same services—which could reflect widespread kickback practices in the industry—but *fair* market value, the price at which an arm's-length market transaction would value these services." *United States ex rel. Gale v. Omnicare, Inc.*, No. 10-cv-127, 2013 U.S. Dist. LEXIS 102658, at *21 (N.D. Ohio July 23,

2013) (emphasis in original); *see also id.* at *20-25 & n.66 ("Under Omnicare's proposed standard, Gale would have to show that Omnicare's prices were below what Montefiore could obtain from other companies. The problem with this construction is that if the industry were permeated with these swapping practices, then all companies might be engaging in kickbacks.").

The Court's observations are mirrored by Relator's expert, Kathy McNamara. Because of the unique regulatory environment and the possibility of widespread illegal competition on price, Relator's fair market value expert, Kathy McNamara, concludes that a market-based approach to assessing fair market value is not appropriate for institutional pharmacy contracts:

> In my opinion it is not appropriate to use the market approach to opine on fair market value prices in this case. The OIG has made it clear that significant discounts offered to SNFs under improper swapping type arrangements by a supplier's competitors may run afoul of the Anti-Kickback Statute. … As the OIG made clear in its Supplemental Compliance Guidance for Hospitals, fair market value cannot be based on comparables if the market rate for comparables is "distorted" by a similar industry practice.
>
> In all instances, Omnicare's competitors stood to gain equally from the profits derived from SNFs other non-Medicare Part A business. A 2008 memorandum from Omnicare's counsel noted, "... the OIG's view is that industry practice is not a justification for actions that may violate the anti-kickback Statute, or a defense against governmental enforcement action." Omnicare was aware that some of its competitors "low ball" their fees for Part A pharmacy services and that for some of its SNF customers, "price is and always will be everything ..." The motivations of some of Omnicare's SNF customers and competitors are suspect and must be examined in light of the SNFs' referrals. For this reason, a study of Omnicare's competitor prices is unwarranted.

McNamara Report 14-15 (footnotes omitted).

Dr. Rao's analysis, by contrast, ignores the regulated marketplace which sets the framework for this case, as well as ignores the most basic facts of the case. He wholly disregards, for example, the abundant evidence produced in this case that Omnicare knew that other pharmacies routinely "low ball" their *per diem* rates (that is, price below cost in order to gain other federal business). *See, e.g.*, McNamara Report 21-22 (describing "low ball" offer given by a competitor, Absolute, which Omnicare matched before losing the contract after Absolute offered an even sweeter deal). He also ignores documentary evidence that the Omnicare Regional Vice President to whom Relator Mr. Gale reported, Rolf Schrader, specifically directed employees to focus narrowly on *per diem* pricing rates when responding to attempts by competitors to wrest business from Omnicare.[1] Dr. Rao instead relies upon abstractions purportedly, and inapplicably, derived from economic theory. He provides no original analysis or data on how Omnicare's competitors do price their drugs, but even if he did, the documentary evidence produced in this case provides a far better and clearer picture of competitors' behavior.

Most critically, Dr. Rao's analysis ignores controlling regulations. It simply does not matter whether Omnicare's illegal inducements were in part caused by competition. Either way, they were still illegal inducements. As Omnicare's own counsel noted in a 2008 memorandum, "the OIG's view is that industry practice is not a justification for actions that may violate the anti-kickback Statute, or a defense against governmental enforcement action."[2]

In sum, Dr. Rao's analysis of competition is not reliable under *Daubert* because, by ignoring illegal practices by competitors and applicable anti-swapping regulations, his report is not "based on sufficient facts or data." Fed. R. Evid. 702(b). It is also inadmissible because it applies principles or methods (market valuation) that—while potentially reliable in other cases—cannot be applied reliably in this case. Fed. R. Evid. 702(d).

B. Dr. Rao's claims to the significance of number of Omnicare's *per diem* facilities are irrelevant and not based on expertise.

[1] In a July 2008 email, attached hereto as Exhibit A, Mr. Schrader advised that, in such circumstances, "[f]irst thing you do is check your contract terms. [The facility has] a great per diem so [Omnicare competitor] Absolute would really have to low ball." [OMNIe00000147].

[2] *See* May 13, 2008 Reed Smith Legal Memorandum, attached hereto as Exhibit B (OMNie00027351), also cited in McNamara Report 14-15 n.35.

Dr. Rao claims that Omnicare's Part A prices do not qualify as kickbacks because *per diem* facilities currently comprise a small percentage of all the facilities with which Omnicare contracts, and that percentage has been decreasing over time. *See* Rao Report ¶ 42. This baseless assertion is not derived from any economic expertise on Dr. Rao's part. Nor is the absolute number of *per diem* contracts or the percentage of contracts using *per diems* relevant to Omnicare's intent.

Dr. Rao argues that because Omnicare does not sign cut-rate *per diem* contracts with many of its clients, the lowball *per diems* it *did* offer were not inducements. This facile argument is premised upon on the assumption that if kickbacks were really so lucrative, Omnicare would have used them in all of its contracts. *See, e.g.*, Rao Report ¶ 42 ("If Medicare Part A per diem contracts represented some form of 'kickback' that generated more business for institutional pharmacies, the expectation would be that their use would be pervasive and increasing."). Dr. Rao's conclusion is precisely the sort—unsupported, based in no part on expertise—that *Daubert* was designed to prevent from confusing a jury.

That Omnicare does not pay kickbacks to all of the facilities with which it does business, furthermore, is irrelevant under Rule 401. Surprisingly for an economist, Dr. Rao ignores the possibility that Omnicare selectively engaged in kickbacks only when it was economically rational to do so, here to secure the patient referral stream. Indeed, it would make little sense were Omnicare *not* to limit the scope of its cut-rate *per diem* deals: not only is any illegal conduct inherently risky, but also, lowball *per diems*, standing alone, are money losers.

What is economically rational, as Dr. Rao himself confirms, is that Omnicare prefers not to lose money on Part A business (when it doesn't have to). *See, e.g.,* Rao Report ¶¶ 38, 40. Consistent with this objective, when it is necessary to gain a facility's lucrative other government healthcare business, Omnicare signs sweetheart *per diem* deals without reservation. Thus, Omnicare's ability to secure some facilities' business without resort to *per diem* kickbacks does not mean that its unprofitable *per diem* deals with other facilities are not intended to induce those facilities to sign up with Omnicare. Dr. Rao's conclusion is irrelevant under Rule 401, as one has no bearing on the other.

Dr. Rao's statement that *per diem* contracts have become less frequent of late is likewise irrelevant. The evidence speaks for itself, and the extent of Omnicare's kickbacks—and whether they diminished over time—has no relevance to liability. Dr. Rao is not being offered as a damages expert, and on this point, none is needed.

In sum, because Dr. Rao's claims about the number of facilities that enjoyed *per diem* kickbacks are not based on expertise,[3] cannot "help the trier of fact to understand the evidence or to determine a fact in issue,"[4] and are irrelevant under Rule 401, they are inadmissible.

C. Dr. Rao's analysis of *per diem* pricing and risk sharing is unreliable, and irrelevant, because it ignores basic economic principles and the facts of the case.

Dr. Rao argues that institutional pharmacies like Omnicare prefer fee-for-service contracts while facilities prefer *per diem* arrangements, and concludes that *per diem* contracts arose because facilities sought to place some of the risk of having especially sick patients on Omnicare. *See* Rao Report ¶¶ 30-42.

Even if that conclusion were true—or if were drawn from any expertise of Dr. Rao's—there is no evidentiary basis upon to admit it here. Discovery in this case has established which arrangements Omnicare and the facilities favor; Dr. Rao's opinions of these preferences are pure speculation. Further, any purported business preferences generally harbored by institutional pharmacies or nursing facilities in the industry are irrelevant to whether Omnicare here offered illegally low *per diem* Medicare Part A contracts to facilities for the purpose of inducing the rest of a facility's business—including the rest of its federal program business. The benefit received by facilities cannot adequately explain the business purpose of the *per diem* contracts offered by Omnicare. As a "rational economic actor[]," *id*. ¶ 31, Omnicare surely understands that by absorbing some of the facility's risk, Omnicare is providing an added benefit, which would justify charging the facility more—that is, a risk premium. Thus, if the only purpose of *per diem* contracts were to place some risk on Omnicare, one would expect that Omnicare's *per diem* pricing would be *higher* than its fee-for-service pricing. Instead, however, *per diem* contracts—in contrast to fee-for-service contracts—were routinely priced below Omnicare's costs.

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[3] *See* Fed. R. Evid. 702(c) & (d).

[4] Fed. R. Evid. 702(a).

D. Dr. Rao's analysis of "loss leaders" misconstrues the payment structure underlying Omnicare's business.

Dr. Rao asserts that Omnicare's negative-margin *per diems* cannot be "loss leaders." In support of this claim, he argues that, because they are well informed consumers not unaware of differential pricing across patients, nursing homes are not susceptible to such a strategy. *See* Rao Report ¶ 74. But Dr. Rao wholly ignores the fact that nursing homes only pay for patients covered by Medicare Part A—not patients covered by Part D or Medicaid, whose bills are paid by the government.

Dr. Rao's entire analysis is based on the incorrect assumption that nursing home bills are charged to a single payor, ignoring the basic method of Omnicare's kickback scheme: one payor (the nursing home facility) pays the low kickback price, and a different payor (the federal government) pays the higher price from the resulting referral. This practice is precisely what Congress outlawed in enacting the Anti-Kickback Statute.

When a facility negotiates with Omnicare to provide Part A services, that facility is also "selling" Omnicare the opportunity to engage in government-paid Part D and Medicaid business. While a rational facility is highly sensitive to Omnicare's Part A pricing (because the facility must pay Omnicare's fees, whether *per diem* or on a fee-for-service model), Omnicare's Part D and Medicaid pricing is irrelevant to the facility's willingness to contract with Omnicare. Because Dr. Rao ignores this basic distinction, his conclusion that Part A *per diem* pricing cannot be a loss leader is unreliable and unhelpful to the trier of fact.

E. Dr. Rao's conclusions about a supposed lack of anticompetitive pricing in the industry are irrelevant to the kickback claims in this case.

Dr. Rao's oft-repeated claims that Omnicare is not engaged in anticompetitive pricing, *see* Rao Report ¶¶ 75-76, are wholly irrelevant to this case. Relator Gale does not raise an antitrust claim. Nor does Mr. Gale argue that Omnicare attempted to drive out competitors by pricing below cost. Perhaps Omnicare is concerned about liability in some other case, but for present purposes, Dr. Rao's conclusions about anticompetitive pricing are irrelevant and inadmissible under Rule 401.[5]

F. Dr. Rao's claim that the government was not harmed by Omnicare's kickback scheme is irrelevant as a matter of law.

Dr. Rao's argument that Omnicare's scheme did not harm the government is not only incorrect, but also irrelevant. Dr. Rao ignores controlling law which provides that the damages to the government arising from kickback equals the amount paid on claims resulting from the kickbacks, regardless of whether the amounts paid were inflated by kickbacks.

[5] Even to the extent that Dr. Rao's conclusions that Omnicare was not engaged in anticompetitive pricing might have some marginal relevance, its probative value would be outweighed by its potential to confuse the jury, and would therefore properly be excluded under Rule 403. *See United States v. Semrau*, 693 F.3d 510, 523 (6th Cir. 2012) (noting that Federal Rule of Evidence 403 "permits a court to exclude relevant evidence if its probative value is substantially outweighed by a danger of confusing the issues or misleading the jury").

Compliance with the Anti-Kickback Statute is a condition of payment for federal healthcare programs. *See, e.g., United States ex rel. Daugherty v. Bostwick Labs.*, 2012 U.S. Dist. LEXIS 178641, at *15 (S.D. Ohio Dec. 14, 2012) ("[C]ompliance with the Anti-Kickback Statute is a condition of payment by the Medicaid program."); *United States ex rel. McDonough v. Symphony Diagnostic Servs., Inc.*, 2012 U.S. Dist. LEXIS 48026, at *4-5 (S.D. Ohio Feb. 27, 2012); *United States ex rel. Barrett v. Columbia/HCA Healthcare Corp*., 251 F. Supp. 2d 28, 32 (D.D.C. 2003). If a participant in a federal healthcare program does not comply with the Anti-Kickback Statute, no payment is due. As a result, the measure of damages in an FCA case based on violations of the AKS is the total value of the government's payments on claims resulting from the kickbacks.

Among the reasons why damages are equal to the value of the resulting claims is that it is impossible to know what the government would have paid in a hypothetical world in which no kickbacks were paid. It is unknown, for example, whether facilities were motivated to refer additional Part D or Medicaid business in order to reward Omnicare for its sweetheart Part A deals, thereby resulting in overprescribing and an accompanying increase in government expenditures. The uncertainty is especially great where, as here, the largest single player in the institutional pharmacy market, Omnicare, is paying the kickbacks. *See* Rao Report ¶ 55.

But even if we could be certain that the government would have paid precisely the same price for healthcare absent kickbacks, the measure of damages would still equal the total value of the resulting claims for payment. That is because the Anti-Kickback Statute is concerned not just with *how much* the government pays, but *who receives* a given federal healthcare dollar. The government is harmed when it gives a dollar to a doctor or pharmacy due to a kickback, because without the kickback, it would have given the dollar to a doctor or pharmacy who played by the rules. Inflated prices are not the only evil the AKS seeks to address.

Judge Easterbrook explained these principles with characteristic lucidity in *United States v. Rogan*, 517 F.3d 449, 453 (7th Cir. 2008):

> Nor do we think it important that most of the patients for which claims were submitted received some medical care—perhaps all the care reflected in the claim forms. . . . The government offers a subsidy (from the patients' perspective, a form of insurance), with conditions. When the conditions are not satisfied, nothing is due. Thus the entire amount that Edgewater received on these 1,812 claims must be paid back. Now it may be that, if the patients had gone elsewhere, the United States would have paid for their care. Or perhaps the patients, or a private insurer, would have paid for care at Edgewater had it refrained from billing the United States. But neither possibility allows Rogan to keep money obtained from the Treasury by false pretenses, or avoid the penalty for deceit.

But the principle is not limited to Medicare, or even to kickbacks: across many areas of law, "the amount of the government's damages equals the full amount that it paid out due to the false claims." *United States ex rel. Freedman v. Suarez-Hoyos*, 2012 U.S. Dist. LEXIS 135230, at *11-12 (M.D. Fla. Sept. 21, 2012). *See, e.g., United States ex rel. Liotine v. CDW Gov't, Inc.*, 2012 U.S. Dist. LEXIS 94837, at *32 (S.D. Ill. July 10, 2012) ("[C]ompliance with the [Trade Agreements Act, prohibits government purchase of certain products from certain countries] is a precondition that must complied with before a sale is permitted. Thus, if it is proven that CDW-G knowingly sold the government products in violation of the TAA, then the correct measure of damages would be the entire amount paid for those products."); *United States v. TDC Mgmt. Corp.*, 288 F.3d 421, 428 (D.C. Cir. 2002) (upholding use of a "but-for" measure of damages where government would have paid nothing to contractor had the contractor disclosed material information); *United States ex rel Longhi v. Lithium Power Techs., Inc.*, 575 F.3d 458, 473 (5th Cir. 2009) (affirming damages award equal to amount government paid in research grants where recipient had misstated its qualifications).[6] When the government buys goods or services, it is entitled to decide who receives that money and for what reason, not just in how much it spends, and this entitlement is enforceable.

Thus, Dr. Rao's conclusion that the government would have paid the same price absent kickbacks is irrelevant in the word's most literal sense. Even if true, that fact would not affect the damages in this case *at all*. Therefore, because the fact of whether the government would have received a different price is not "of consequence in determining the action," Fed. R. Evid. 401(b), Dr. Rao's conclusions on it should be excluded.

G. Dr. Rao's claims that Omnicare acted in an economically rational, pro-competitive way are unreliable and irrelevant.

At ¶¶ 69-72, Dr. Rao argues that Omnicare may have acted in an economically rational, pro-competitive way when it priced *per diem* drugs below its total costs. According to Dr. Rao, "[p]ricing below average total cost frequently may be economically rational." *Id.* ¶ 69. But Dr. Rao's analysis leaves out a key detail: pricing below total cost is precisely what government guidance has said is forbidden. *See* OIG Advisory Opinion No. 99-13 (November 30, 1999), attached hereto as Exhibit C ("[W]hen determining whether a discount is below cost, we look, for example, at the total of all costs (including labor, overhead, equipment, etc.) divided by the

[6] Of course, even if actual damages in this case were zero—and they are not—the penalty of at least $5500 per violation still attaches. *See, e.g.*, *Bly-Magee v. California*, 236 F.3d 1014, 1017 (9th Cir. 2001) ("The False Claims Act requires a court to award not less than $5,000 and not more than $10,000 for each false claim or statement submitted to the government, even if no damages were caused by the false submissions. No damages need be shown to recover the penalty under the False Claims Act." (internal quotation marks and citations omitted)); *United States ex rel. Resnick v. Weill Med. College of Cornell Univ.*, 2010 U.S. Dist. LEXIS 11019, at *20 (S.D.N.Y. Jan. 21, 2010) ("As for Defendants' contention that the Government was not harmed because it did not fund this grant, damages are not an element of an FCA claim and [plaintiff] can recover the civil penalty even though the United States was not harmed.").

total number of laboratory tests.”). Because Dr. Rao once again ignores the governing regulatory framework, his conclusions are unreliable and irrelevant.

III. CONCLUSION

For the foregoing reasons, Dr. Rao's expert report should be excluded in its entirety.

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Respectfully submitted,

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